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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,012	03/08/2006	**Frank Cuttitta**	4239-82094-06	4600

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,012	CUTTITTA ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,5,9-11,17,20,26,29,35,38,44,47,49,53,55,57,59,62-63,74,76-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,5,9-11,17,20,26,29,35,38,44,47,49,53,55,57,59,62,63,74,76 and 77.

DETAILED ACTION

Pursuant to the claim amendments filed on March 8, 2006, the Restriction Requirement mailed on October 1, 2008 has been vacated and is replaced by the current Restriction Requirement. The time of response has been restarted.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Lack of Unity – Fifteen Groups of Claims

Group I, claim 1, drawn to a complex comprising a compound of one of formula I-VIII, XII or XIII, in association with an adrenomedullin (AM) peptide.

Group II, claim 5, drawn to a complex comprising a compound of one of formula XIV.

Group III, claims 9, 10 and 53 drawn to a pharmaceutical composition comprising a compound of one of formula I-VIII, XII or XIII as defined in claim 1, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier.

Group IV, claims 55, 76 and 77 drawn to a kit suitable for treating a subject suffering from a condition mediated by an aberrant expression and/or activity of gastrin releasing peptide (GRP), comprising a pharmaceutical composition comprising one or more of the compounds of formula XIV, XVI or XVII as defined in claim 76.

Group V, claims 11 and 17, drawn to a method for inhibiting an activity of an AM peptide, comprising contacting the peptide with an effective amount of a pharmaceutical comprising the compound of one of formula I-VII as defined in claim 9.

Group VI, claims 20 and 26, drawn to a method for stimulating an activity of an AM peptide, comprising contacting the peptide with an effective amount of a pharmaceutical

Group VII, claims 29, 35, 62, and 63, drawn to a method for inhibiting an activity of a GRP peptide, comprising contacting the peptide with an effective amount of a pharmaceutical composition comprising compound of XIV or XVI as defined in claim 76.

Group VIII, claims 38 and 44, drawn to a method for stimulating an activity of a GRP peptide, comprising contacting the peptide with an effective amount of a pharmaceutical composition comprising the compound of formula XVII, as defined in claim 76.

Group IX, claim 47, drawn to a method for detecting an AM petptide, comprising contacting a sample suspected of comprising the peptide with a pharmaceutical composition of one or more detectably labeled compounds of formula I through VIII or XII through XIII, as defined in claim 76.

Group X, claim 49, drawn to a method for detecting a GRP peptide, comprising contacting a sample suspected of comprising the peptide with a pharmaceutical composition one or more detectably labeled compounds of formula XIV, XVI or XVII, as defined in claim 76.

Group XI, claim 57, drawn to a kit suitable for detecting a AM peptide.

Group XII, claim 59, drawn to a kit suitable for detecting a GRP peptide, comprising a pharmaceutical composition comprising one or more compounds selected from formula XIV, XVI, XVII and XV, as defined in claim 49, wherein the compound is detectably labeled.

Group XIII, claim 74, drawn to a method for treating low blood pressure or an eating disorder in a subject in need of such treatment, comprising administering to the subject an effective amount of a pharmaceutical composition comprising the compound of formula XV as defined in claim 49.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: a special technical feature is absent given that the compounds claimed of formula IV are not novel (Tmej et al, page 2, Arch. Pharm. Med. Chem, 331, 233-240, 1998). Further, the compounds of formula XVI, claim 5, are not novel (see U.S. 6,077,928, Polymer Example 2). Therefore, a lack of unity of invention is proper.

Election of Specie Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a

single general inventive concept under PCT Rule 13.1. Specifically, with the election of Groups I-XIII, applicant is required to elect:

one specific compound

Additionally, with the election of Groups V-VIII, or XIII:

one disease

If applicant elects a specie from the above specie elections which is not found in the instant disclosure as filed, specie election may be considered new matter. Additionally, applicant is required to provide a chemical structure of the elected compound as well as to **specify** precisely where the elected compound can be found in the instant disclosure.

Each compound has a different structure and thus different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility and modes of action. Furthermore, the search for one specie will not lead to information regarding another, and vice versa. Because these inventions are distinct for the reasons given above and the search required for one species is not required for another, the restriction requirement is deemed proper.

Each disease has a different and distinct etiology and pathophysiological manifestations, and that each is differently treated. Such is sufficient to indicate that each of the methods of treating the presently claimed disease states is differently searched in the patent and non-patent literature and that a search for one disease will not necessarily result in a comprehensive search of any one or more of the other diseases listed. As a result, an undue burden would be placed on the Examiner to search each of Applicant's presently claimed species. MPEP 809.02(d) states "[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly

extensive and burdensome search would be necessary if all the claimed species were to be examined simultaneously.

Applicant is required, to reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicated which are readable upon the elected species. MPEP 809.02(a).

Applicant is advised that a reply to this requirement may to be complete must include (i) an election of a species or invention to be examined even though the requirement is traversed (37 CFR 1.143) and (ii) the identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a fight to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as
an election with traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.170).

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614